

## Right to Life Michigan 12/4/18

Mr. Chairman, members of the committee, thank—you for allowing me to speak on SB 1198 – the telemedicine abortion ban sunset repealer. The bill maintains the status quo, maintains the ban on telemedicine abortions, and is in keeping with current FDA requirements. That said, I'd like to give you a little background on medication abortions and the telemedicine ban.

There were 26,594 abortions last year in this state. 9,422 or 35% were from the abortion pill. In 2013, the first year the ban was in place, there were 26,100 abortions with 5,103 by the abortion pill representing 19% of the total. So, access to chemical abortions has not been impeded and the number of women using the abortion pill has increased considerably over the past 6 years despite the ban on telemedicine abortions.

The abortion pill or RU-486 is a 2-pill regimen. The first pill, Mifeprex, is given to the woman at the clinic. This pill ensures fetal demise. The second pill is taken 24-48 hours later and causes uterine contractions which expels the now dead fetus. This is not to be confused with the morning after pill which is sold over the counter without a prescription and is designed to prevent conception. The abortion pill, Mifeprex, is designed to terminate an already existing pregnancy up to 10 weeks gestation.

The abortion pill was originally approved for use in the US in the year 2000 and the FDA placed a REMS on the drug. A REMS, or Risk Evaluation and Mitigation Strategy, is a safety strategy to manage a known or potential serious risk associated with a drug. There are 76 drugs which require a REMS – Mifeprex is one of them. Included in the abortion pill REMS is the requirement that **"Mifeprex must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals by or under the supervision of a certified perscriber."** This statement precludes the use of telemedicine for medical abortions.

In 2012, Michigan placed a preemptive ban on telemedicine abortions that complied with the FDA recommendations. Telemedicine abortions have never taken place in Michigan. However, Governor Snyder required the ban to sunset in 6 years – which takes place on December 31<sup>st</sup> of this year if we don't repeal the sunset. At the time, telemedicine was not well established, and there was some speculation that the FDA would change its recommendations. It has become clear in the past 6 years that the ban is still needed and very much in line with the FDA recommendations.

In 2016, Danco Pharmaceuticals, the manufacturer of Mifeprex, submitted a supplemental application to the FDA asking that the FDA consider removing the REMS, change the dosing regimen, and increase the gestational age limits.

The scientists, doctors and experts at the FDA reviewed the clinical trial data, went over additional studies, took input from experts in the field and concluded that **"After reviewing the supplemental application, the agency determined that a REMS continues to be necessary to ensure the safe use of Mifeprex."**

BTW....that was under the Obama Administration. The FDA did, however, increase the age limits from 7 weeks to 10 weeks, changed the dosing, and made some changes to the REMS – but they kept the requirement that Mifeprex only be dispensed in clinics, medical offices or hospitals by certified prescribers.

A review of the data submitted to the FDA from **several large clinical studies.....not self-reported complications**, shows that 15% of women experienced: nausea, weakness, fever/chills, vomiting, headache, diarrhea, or dizziness. 15% of 9,422 (the number of chemical abortions last year) is over 1,400 women who likely experienced a side effect stemming from the abortion pill. In addition, between 2 and 7% of terminations "failed," depending on the gestational age – meaning they didn't actually cause the abortion, and the women needed follow-up surgical abortions. Since the FDA increased the age limits in 2016, we can expect more "failures" because the older the baby, the more likely the abortion pill is to fail. This means that between 188-659 Michigan women will need a doctor who will be available to examine her and provide her with a follow-up abortion – telemedicine makes that impossible.

In March of **this year**, a group of Representatives asked the Government Accountability Office to review the FDA's approval methods used for Mifeprex. The GAO concluded that, "The Food and Drug Administration (FDA) followed its standard review process when it approved the application and revised labeling reflecting certain changes, including the indication and dosing regimen, for the drug Mifeprex. It based its approval on reviews of peer-reviewed published studies, articles, and other information submitted by Mifeprex's sponsor." In other words, there was no foul play, no favoritism on the part of the FDA, and no increased scrutiny because it deals with abortion. The GAO report concluded that the FDA did its job and the precautions it put in place were based on the same standards and protocols it uses for other drug approvals. **The REMS is still necessary despite the fact that some have decried the existence of the it and have openly criticized the FDA for continuing to impose it.**

Telemedicine abortions leave women with no doctor available in the event that she suffers a serious side effect, an incomplete abortion or has severe bleeding. With telemedicine, the "doctor" could be in another state or another country hundreds or thousands of miles away. With the known "failure" rate of the abortion pill and need for the abortion to be completed surgically, hundreds of Michigan women would be left vulnerable in a telemedicine situation. Not to mention the upwards of 1,400 women who will experience some form of side effect and may want to follow-up with their doctor. The ban on telemedicine abortions is a matter of common sense and safety.

SB 1198 removes the sunset and keeps the ban on telemedicine abortions in place which complies with the current FDA recommendations. Telemedicine is a great option for some medical conditions. **Abortion is not one of them.** I urge your support of SB 1198. Thank you.

